

BRAZIL - New Bioinputs Law 15.070/24

What is going to change?

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Brief Introduction

PhD Entomology - UFV Brazil/UNL Nebraska
MSc Microbiology / Major in Biology

Co-founder of Cesis - Regulatory Consultancy Company 2005

Co - founder of REDLATAM

ISO 17025 / GLP Leader and Technical Inspector

Former IBAMA Consultant

CV Lattes <http://lattes.cnpq.br/6548097356823930>



Where we are



RED LATAM
AMPLIANDO FRONTERAS



CESIS



CESIS

Who we are

- **20 years old company**
- **Passionate for Innovation**
- **Multidisciplinary Team**
- **Committed to Sustainability**
- **Former Government Consultants**
- **GLP and ISO 17025 inspectors**
- **Former GLP Lab Study Directors**
- **CESIS is co-founder of RED LATAM**
- **Consultancy Members / BR actual
President**

Who we are
REDLATAM
Regulatory Sisters
Companies joining
forces to help grow
Bioinputs market in Latin
America



Where we are

- Argentina
- Brazil
- Bolivia
- Chile
- Colombia
- Costa Rica
- Ecuador
- Guatemala
- Honduras
- Mexico
- Nicaragua
- Panama
- Paraguay
- Peru
- Rep. Dominicana
- Uruguay



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Why Latin America is Important?

Latin America is one of the most important regions in agricultural commodities and natural resources global trade.

Latin America's total exports exceeded US\$ 1.4 trillion (World Bank 2022)

BRAZIL EXPORTS US\$ 137,7 bn/2024.



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BIOINPUT'S LAW 15070/2024

Bio-input: product, process, or technology of **plant, animal, or microbial origin**, including those derived from **biotechnological processes**, or structurally similar and functionally identical to those of natural origin, intended for use in the production, protection, storage, and processing of **agricultural products or in aquaculture or planted forest production systems**, that **interferes** with the **growth, development, and response mechanisms** of **animals, plants, microorganisms, soil, and derived substances**, and interacts with physical-chemical and biological products and processes."



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BIOINPUT'S LAW 15070/2024

Regulates:

Biostimulants	Growth/inhibitors substances
Semiochemicals	Biochemicals
Phytochemicals	Biofertilizers
Metabolites/Organic macromolecules	
Biological control agents	Inoculants
Soil amendments	

New Definitions

New Inspection System

New Government fees



The goal is to address specific definitions in Normatives more flexibility in terms of definitions/concepts



**OPPORTUNITY TO REWRITE
DEFINITIONS AND THINK
DIFFERENTLY**

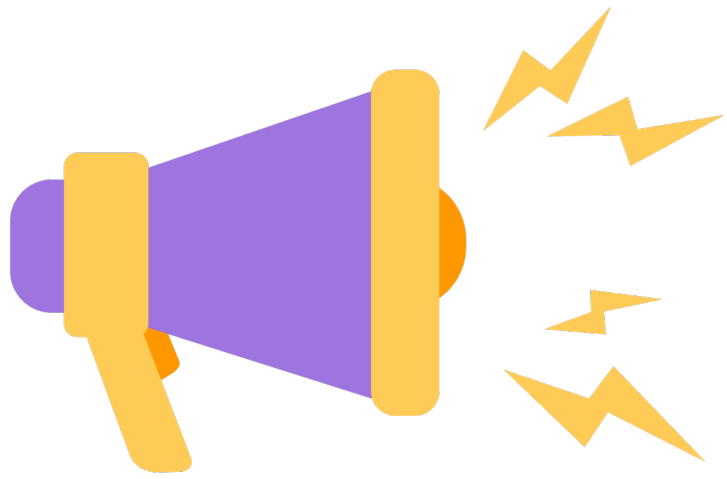


- on-farm activity is now regulated
bio-input produced exclusively for
personal use is exempt from
registration
- Registration is mandatory for
Inoculum and end use product



MAPA is in **charge**
abiotic / biotic products

ANVISA/IBAMA is also in the process
but for **NEW PRODUCTS** - FOR CROP
PROTECTION



"Article 31. Until the regulation of this Law, the process for new registrations will follow the provisions set out in the specific regulations that governed the matter".

NOTHING HAS CHANGED YET!



BIOSTIMULANT X BIOFERTILIZER



Where is the term
BIOSTIMULANT fits in Brazilian
Legal Frame ???

Biotic Stress



Normative 01/2023

- i - In addition to pest control, this normative included the registration of defoliating agents, desiccants, growth stimulators and inhibitors, whose active ingredient is a microorganism or metabolism arising from its fermentation and/or growth

BIOESTIMULANTS.



Biostimulant

microorganisms and/or **metabolites** applied with the function of stimulating physiological processes of the plant that result in the prevention or response to plant stress, which may favor the control of a population or the action of another living organism considered harmful, or even, it may act as a defoliant or desiccant of plants, growth stimulators and inhibitors

Biocontrol Registration





WHO IS IN
CHARGE

MAPA

ANVISA

IBAMA



**WHO IS IN
CHARGE**
MAPA, ANVISA, IBAMA

- **TOX & ECOTOX - GLP**
- **Field Trials in Brasil**
- **Government Fees**
- **Average 18 months Gov Analysis**



REGISTRANT RESPONSABILITIES

- **Brazilian Company**
- **Labels and package updated and as "approved" by the Authorities**
- **Quality Control**
- **Packaging return**
- **Comply with adjacent legislation**



If Biostimulant is not a microbe
and/ or metabolite??

Biochemical Product

naturally occurring chemicals with a non-toxic mechanism -
used to control diseases or pests a- promoting chemical or
biological processes,

Including:

I – hormones and growth regulators;

II - enzymes: **naturally** occurring proteins

Proteins include peptides and amino acids, **but do not include
toxic proteins and those derived from GMOs.**

Abiotic Stress Biostimulant



Definitions:

- **Inoculants** : product containing microorganisms with a favorable growth performance

- **Biofertilizers**: product containing active components, improving plant performance and free from substances prohibited by organic regulation, stimulant effect and fermentation process



Registration process



One Legal Authority

MAPA

field trials for **New Product** Inoculants

Biofertilizers (green house)

regular inoculants - no field trials

Registration by crop / by strain

Registration process




No GPL lab estudies required
fiedl trials underground
label by claim

Registrant - Legal BR Company

Is going to change by New Law????

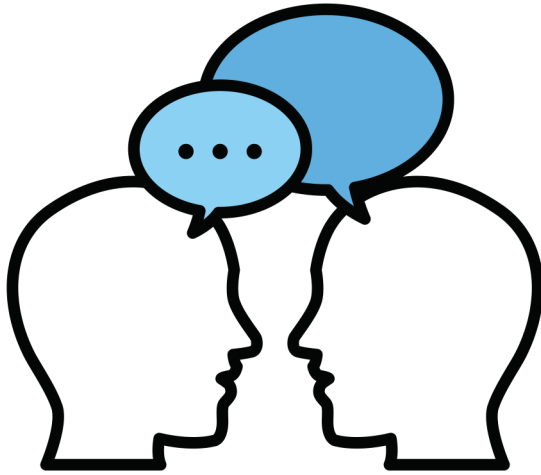
Any New Product, national or imported, which does not have a historical of use in Brazil, in any of its technical aspects, will only have its registration granted after a conclusive technical-scientific report, issued by an official or accredited Brazilian research body, which attests to the feasibility and efficiency of its agricultural use, and the research work with the product, when necessary, they should not be extended for a period longer than three crop seasons, except when technical conditions require their extension.



The label may not contain a name, symbol, figure, design or any other indication that induces error or misunderstanding as to the origin, nature or composition of the product, nor attribute to it a quality or characteristic that it does not possess or that is not related to fertilizers, correctives, inoculants or biofertilizers.



**What comes
next???**



- **Phytochemical products**
- **Normative**
- **New definition for biostimulant/biofertilizer**
- **Multiple uses - one single regulation?**
- **Intellectual property for microorganisms?**

Obrigada



Thank You



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Questions?

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